

**Section 1.1a - 510(k) Summary in accordance with 21 CFR Part 807.92, Section a**

1. Submitter's contact name, address, telephone/fax number, date prepared:

Angela Van Arsdale  
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Hitachi Aloka Medical, Ltd.  
10 Fairfield Blvd  
Wallingford CT 06492  
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APR 5 2013

Date Prepared: February 4, 2013

2. Device / Common / Classification Name:

Hitachi Noblus™ Diagnostic Ultrasound System  
Common name - Diagnostic Ultrasound System and Transducers  
Classification name - System, Imaging, Pulsed Doppler, Ultrasonic

3. Substantially Equivalent Device(s):

Hitachi HI VISION Avius Diagnostic Ultrasound Scanner [K102901]

4. Device Description:

An ultrasound diagnostic system with the following features:

- o Ultrasound transducer(s) – to generate the transmitted ultrasound energy and detect the reflected echoes
- o Ultrasound transducer accessories (standard and optional) - to maximize functional usage of transducer(s) in various modes of operation
- o A computer system - to control the transducer and analyze the signals resulting from the reflected echoes
- o A standard Lithium ion computer battery – to allow for system portability
- o A video monitor with optional image recorder – to display the computed image or derived Doppler data

5. Indication for Use:

The Hitachi Noblus™ Ultrasound Diagnostic System is intended for use by trained personnel (doctor, sonographer, etc.) for the diagnostic ultrasound evaluation of Abdominal, Cardiac, Intra-operative, Fetal, Pediatric, Small Organ, Peripheral vessel, Biopsy, Trans-rectal, Trans-vaginal, Musculoskeletal, Neonatal, Cephalic, Adult Cephalic, Endoscopy, Intra-luminal, Gynecology, Urology, and Laparoscopic clinical applications.

The modes of Operation of the Hitachi Noblus™ Ultrasound Diagnostic System are B mode, M mode, PW mode (Pulse Wave Doppler), CW mode (Continuous Wave Doppler), Color Doppler, Amplitude Doppler (Color Flow Angiography), TDI (Tissue Doppler Imaging), 3D Imaging, 4D Imaging, and Real Time Tissue Elastography.

6. Comparison to predicate device:

The Hitachi Noblus™ Diagnostic Ultrasound device is technically comparable and substantially equivalent to the Hitachi HI VISION Avius Diagnostic Ultrasound Scanner [K102901]. Both systems are track 3 systems that incorporate the same fundamental and scientific technologies with the exception of the following features:

- STIC (Spatio Temporal Image) which is a new feature when compared to predicate [K102901]. The STIC feature is not new to the Hitachi Ultrasound systems; it has been previously cleared in the HI VISION Ascendus system via K110673.
- Standard Lithium ion Computer battery for use in the "portable" option
- The accessories; a Biopsy Adapter [EZU-PA7L1] and a Coupler [EZU-TEATC2] which are similar in intended use and function as the accessories for the predicate device HI VISION Avius [K102901]; has historical utilization on Hitachi Ultrasound transducers and have been previously cleared on the HI VISION Ascendus via K110673.

Both the subject device and predicate device systems have the same intended use/ indications for use.

**Section 1.1b - 510(k) Summary in accordance with 21 CFR Part 807.92, Section b**

1. Non-clinical Testing:

No new hazards were identified with the subject device. The subject device and its transducers have been evaluated for acoustic output, biocompatibility, cleaning & disinfection effectiveness, electromagnetic compatibility, as well as electrical and mechanical safety, and have been found to conform to applicable medical device safety standards.

2. Clinical testing:

None required

3. Conclusions:

The Hitachi Aloka Medical, Ltd. Noblus™ Diagnostic is substantially equivalent in safety and effectiveness to the predicate device;

- The predicate and subject devices are both indicated for diagnostic ultrasound imaging and fluid flow analysis.
- The predicate and subject devices have the same gray scale and Doppler capabilities.
- The predicate and subject devices have the same essential technology for imaging, Doppler functions, and signal processing.
- The predicate and subject devices have acoustic level below the Track 3 FDA limits.
- The predicate and subject devices are manufactured in accordance to FDA 21 CFR 820 Quality System Regulations.
- The predicate and subject devices are designed and manufactured to the same electrical and physical safety standards.
- The predicate and subject devices are manufactured with materials that have been tested in accordance to tripartite biocompatibility guidance and ISO 10993-1; all biocompatibility testing has been conducted in accordance to each component material characterization, type of body contact, and duration contact risk profile.
- The predicate and subject devices are designed to be re-usable and provide instructions for cleaning, disinfection, and sterilization in the Ultrasound system and transducer manuals.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-002

April 5, 2013

HITACHI ALOKA MEDICAL LTD  
c/o Angela Van Arsdale  
Regulatory Affairs/Quality Assurance Manager  
10 Fairfield Blvd  
Wallingford, CT 06492

Re: K130308

Trade/Device Name: Noblus™ Ultrasound Diagnostic System  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic Pulsed Doppler Imaging System  
Regulatory Class: Class II  
Product Code: IYN, ITX, IYO  
Dated: February 4, 2013  
Received: February 7, 2013

Dear Angela Van Arsdale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Noblus™ Ultrasound Diagnostic System, as described in your premarket notification:

Transducer Model Number

<u>C22</u>	<u>EUP-CC531S</u>	<u>L34</u>
<u>C25</u>	<u>EUP-OL334</u>	<u>L44</u>
<u>C41</u>	<u>EUP-R54AW-19,-33</u>	<u>L55</u>
<u>C41V</u>	<u>VC34A</u>	<u>L64</u>
<u>C42</u>	<u>EUP-O54J</u>	<u>S21</u>
<u>C42K</u>		<u>S31</u>

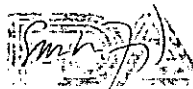
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



for

Janine M. Morris  
Director, Division of Radiological Health  
Office of In Vitro Diagnostics and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications For Use

510(k) Number (if known): K130308

Device Name: Noblus™ Ultrasound Diagnostic System

### Indications for Use:

The Noblus™ Ultrasound Diagnostic System is intended for use by trained personnel (doctor, sonographer, etc.) for the diagnostic ultrasound evaluation of Abdominal, Cardiac, Intra-operative, Fetal, Pediatric, Small Organ, Peripheral vessel, Biopsy, Trans-rectal, Trans-vaginal, Musculoskeletal, Neonatal Cephalic, Adult Cephalic, Endoscopy, Intra-luminal, Gynecology, Urology, and Laparoscopic clinical applications.

The Modes of Operation of the Noblus™ Ultrasound Diagnostic System are B mode, M mode, PW mode (Pulse Wave Doppler), CW mode (Continuous Wave Doppler), Color Doppler, Amplitude Doppler (Color Flow Angiography), TDI (Tissue Doppler Imaging), 3D Imaging, 4D Imaging, and Real Time Tissue Elastography.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   x  

AND/OR

Over-The-Counter Use           

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Device Name: Noblus™ Ultrasound Diagnostic System

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P
	Abdominal	Pa	Pa	Pa	Pa	Pa	Pa	Pa
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic	P	P	P		P	P	P
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic	P	P	P	P	P	P	P
	Adult Cephalic	P	P	P	P	P	P	P
	Trans-rectal	Ph	Ph	Ph		Ph	Ph	Ph
	Trans-vaginal	Pf	Pf	Pf		Pf	Pf	Pf
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P
	Cardiac Pediatric	P	P	P	P	P	P	P
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K102901

\*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging, 3D Imaging, 4D Imaging, Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

*Prescription Use Only (Per 21 CFR 801.109)*

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus™

Transducer: C22K

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K102901

\*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography)

## Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus™

Transducer: C25

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K102901

\*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography)

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excludes neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus™

Transducer: C41

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)	Pc	Pc	Pc		Pc	Pc	Pc
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K102901

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography)

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excludes neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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Office of *In Vitro* Diagnostics and Radiological Health510(k) K130308

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus™  
Transducer: C41V

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	Pe	Pe	Pe		Pe	Pe	Pe
	Trans-vaginal	Pf	Pf	Pf		Pf	Pf	Pf
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K102901

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), Real Time Tissue Elastography.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery.  
(excludes neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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510(k) **K130308**

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus™  
Transducer: C42

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic	P	P	P		P	P	P
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K102901

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), Real Time Tissue Elastography.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery.  
(excludes neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients.

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus™

Transducer: C42K

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Cardiac	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K102901

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography)

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excludes neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients.

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Division of Radiological Health

Office of *In Vitro* Diagnostics and Radiological Health

510(k) K130308

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus™  
Transducer: EUP-CC531S

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	Pe	Pe	Pe		Pe	Pe	Pe
	Trans-vaginal	Pf	Pf	Pf		Pf	Pf	Pf
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K102901

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excludes neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

*Prescription Use Only (Per 21 CFR 801.109)*

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Office of *In Vitro* Diagnostics and Radiological Health

510(k) K130308

## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus™  
Transducer: EUP-O54J

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)	Pb	Pb	Pb		Pb	Pb	Pb
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K102901

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery.  
(excludes neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus™  
Transducer: EUP-OL334

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic	P	P	P		P	P	P
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K102901

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy.

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

Prescription Use Only (Per 21 CFR 801.109)

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus™  
Transducer: EUP-R54AW-19, -33

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric							
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	P
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K102901

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excludes neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

*Prescription Use Only (Per 21 CFR 801.109)*

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus™

Transducer: L34

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K102901

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), Real Time Tissue Elastography

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excludes neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus™

Transducer: L44

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K102901

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), Real Time Tissue Elastography.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excludes neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus™

Transducer: L55

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K102901

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), Real Time Tissue Elastography.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery.  
(excludes neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus™  
Transducer: L64

Intended use: Diagnostic ultrasound imaging or fluid flow analysis if the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	Pa	Pa	Pa		Pa	Pa	Pa
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	Pd	Pd	Pd		Pd	Pd	Pd
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)	P	P	P		P	P	P
	Musculo-skel. (Superfic.)	P	P	P		P	P	P
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K102901

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), Real Time Tissue Elastography.

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery  
(excludes neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus™  
Transducer: S21

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	P	P
	Abdominal	P	P	P	P	P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	P	P
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P
	Cardiac Pediatric	P	P	P	P	P	P	P
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	P	P
	Other (spec.)							

N = new indication. P = previously cleared in K102901

\*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), Tissue Doppler Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery.  
(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus™  
Transducer: S31

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P	P	P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P
	Small Organ (Spec.)							
	Neonatal Cephalic	P	P	P	P	P	P	P
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
	Intra-luminal							
	Other (spec.)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P
	Cardiac Pediatric	P	P	P	P	P	P	P
	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K102901

\*Combination of each operating mode, B, M, PWD, CWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), Tissue Doppler imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery.  
(excludes neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

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## DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Noblus™  
Transducer: VC34A

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined* (Spec.)	Other** (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	P	P
	Abdominal	P	P	P		P	P	P
	Intra-operative (Spec.)							
	Intra-operative (Neuro.)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Spec.)	P	P	P		P	P	P
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
Cardiac	Intra-luminal							
	Other (spec.)							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (card.)							
	Other (spec.)							
Peripheral Vessel	Peripheral vessel							
	Other (spec.)							

N = new indication. P = previously cleared in K102901

\*Combination of each operating mode, B, M, PWD and Color Doppler.

\*\*Amplitude Doppler (Color Flow Angiography), 3D Imaging, 4D Imaging

Additional Comments:

Subscript "a": Includes imaging for guidance of percutaneous biopsy of abdominal organs and structures (including amniocentesis).

Subscript "b": Includes imaging of organs and structures exposed during surgery.

(excluding neurosurgery and laparoscopic procedures).

Subscript "c": Includes thyroid, parathyroid, breast, scrotum, and penis.

Subscript "d": Includes thyroid, parathyroid, breast, scrotum, penis, and imaging for guidance of biopsy.

Subscript "e": Includes imaging for guidance of trans-rectal biopsy

Subscript "f": Includes imaging for guidance of trans-vaginal biopsy.

Subscript "g": For pediatric patients

Subscript "h": Includes imaging for guidance of trans-rectal biopsy.

Prescription Use Only (Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)



(Division Sign-Off)

Division of Radiological Health

Office of *In Vitro* Diagnostics and Radiological Health

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